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16
17 **UNITED STATES DISTRICT COURT**
18 **EASTERN DISTRICT OF WASHINGTON**

19 CITY OF SPOKANE, a municipal
corporation, located in the County of
Spokane, State of Washington,

20 Plaintiff,

21 v.

22 MONSANTO COMPANY, SOLUTIA
23 INC., and PHARMACIA
CORPORATION, and DOES 1 - 100,

24 Defendants.

Case No. 15-cv-00201-SMJ

Defendants' Opposition to Plaintiff's
Motion to Exclude Expert Opinions of
Perter G. Shields, M.D.

Hearing Date: March 12, 2020
Time: 8:30 a.m.
With Oral Argument
Location: Richland, WA

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1 **I. INTRODUCTION**

2 Plaintiff seeks to exclude certain testimony of Defendants' expert, Dr. Peter
3 G. Shields ("Dr. Shields")—an expert Plaintiff chose not to depose in this case. Dr.
4 Shields is an oncologist, hematologist and tenured Professor in the Departments of
5 Internal Medicine and Epidemiology at The Ohio State University, where he is the
6 endowed Julius F. Stone Chair in Cancer Research. ECF No. 388-2 at 5. Since
7 2011, he has also held the position of Deputy Director of the Ohio State University
8 Comprehensive Cancer Center. *Id.*

9 During the course of his career, Dr. Shields has been responsible for
10 directing a multidisciplinary and transdisciplinary research program that focuses on
11 identifying the environmental and genetic causes of cancer using epidemiology and
12 biomarkers. *Id.* He has authored more than 240 peer-reviewed scientific papers in
13 the field of molecular and human epidemiology and carcinogenesis. Dr. Shields
14 serves or has served on editorial boards of premier journals in the fields of
15 epidemiology and the causes of cancer, including Carcinogenesis, Molecular
16 Carcinogenesis, Journal of Cancer Epidemiology, and Cancer, Epidemiology,
17 Biomarkers and Prevention. *Id.* at 5-6.

18 In this case, Dr. Shields provides opinions on, among other things, (a) the
19 lack of any causal relationship between PCBs and human cancers based upon the
20 available scientific evidence; and (b) the IARC Working Group's findings (and
21 inappropriate methodologies) related to PCBs and cancers. *Id.* at 7-9. He
22 formulated numerous opinions in his expert report based upon his general scientific
23 and medical knowledge, systematic literature review, and research and clinical
24 practice as a hematologist, oncologist, and cancer epidemiologist. *Id.* at 3.

1 In short, he is overwhelmingly qualified to testify about cancer causation,
2 toxicology, carcinogenesis, epidemiology and hematology and oncology in this
3 matter, along with the methodological deficiencies of the IARC working group's
4 cancer findings. Plaintiff intends to proffer evidence concerning the relationship
5 between PCBs and human cancers. Dr. Shields possesses the appropriate
6 foundation to offer his opinions, which are probative, directly on point, reliable and
7 will assist the jury in the determination of the issues in this case. Consequently,
8 this Court should deny Plaintiff's Motion.

9 **II. ARGUMENT**

10 **1. Dr. Shields' specific causation opinion is probative, not confusing, and based upon reliable scientific methodologies.**

11 Dr. Shields' report contains several opinions related to PCBs and cancer,
12 including the following:

- 13 • "The most important studies for understanding cancer risk in humans are
14 high quality studies that assess human risk at the highest levels of human
15 exposure. These are the occupational studies . . . These studies, in addition to
16 mechanistic data, provide convincing epidemiological evidence that PCBs
17 do not measurably cause human cancers at the highest dose to which
workers have been exposed;" and
- 18 • "Using two weight of evidence reviews and given that there are many
19 studies at high levels of exposure in some workplaces, it is my opinion that
20 there is insufficient evidence that PCBs cause cancer of any type, a
21 conclusion that should provide reassurance for a lack of effect for the
22 general population, including individuals who consume fish from Spokane
River."

1 *Id.* at 7-8. In short, Dr. Shields opines that there is no evidence of a causal
2 connection between PCBs and any type of cancer.

3 Plaintiff does not seek to exclude this opinion. Instead, Plaintiff seeks to
4 preclude Dr. Shields from testifying about specific causation: namely, “the human
5 health effects of exposures to PCBs from the Spokane River.” ECF No. 388 at 3.

6 Plaintiff offers two reasons for its requested exclusion. First, Plaintiff
7 perplexingly argues that Dr. Shields’ specific causation opinion is not probative.
8 *See id.* The alleged human health effects of PCBs, including cancer, are one of the
9 reasons for which Plaintiff claims a nuisance in the Spokane River. *See generally*,
10 ECF No. 1. Testimony that human cancer is not caused or capable of being caused
11 by any known level of PCB exposure, including any purported exposures from the
12 Spokane River, is not only probative and straightforward, but it goes to the heart of
13 Plaintiff’s case. Defendants have the right to dispute, through expert testimony,
14 Plaintiff’s allegations of a causal connection between PCB exposures and cancer.

15 Second, Plaintiff argues that Dr. Shields lacks a proper foundation. Namely,
16 Plaintiff argues that Dr. Shields’ report “does not in any way quantify exposures to
17 PCBs from the Spokane River, discuss exposure pathways or doses, address the
18 existing body burden of persons exposed to PCBs through the Spokane River, or
19 relates PCBs in [the] Spokane River water to a resulting blood serum level or body
20 burden.” ECF No. 388 at 3.

21 Plaintiff clearly misunderstands Dr. Shields’ causation opinion. Dr. Shields
22 concluded, after a systematic review and evaluation of the epidemiological and
23 mechanistic evidence which includes occupational studies of worker populations
24 with the highest known levels of human exposure, general population studies, and

1 studies of populations of heavy fish consumers, that the evidence does not support
2 any conclusion that PCBs cause or are capable of causing human cancers, even
3 among individuals with the highest known levels of human exposures. *Id.* at 7-9;
4 *see* ECF No. 388-2. In short, Dr. Shields' opinion is not qualified by or
5 conditioned upon certain levels of PCB exposure, PCB serum levels, fish tissue
6 concentrations, fish consumption or geographical location. *Id.* It does not matter
7 what a person eats or where a person lives; PCBs do not cause human cancers. *See*
8 *id.* Consequently, Dr. Shields is easily able to opine that there is no evidence that
9 PCB exposures from the Spokane River cause human cancer, because there is no
10 evidence that PCB exposures of any magnitude and from any pathway or location
11 cause human cancer.

12 Plaintiff faults Dr. Shields for not "elaborating" to their liking with respect
13 to Spokane River exposures, but Plaintiff chose not to depose him about his
14 opinions in this case. If Plaintiff desired Dr. Shields to elaborate on any one or
15 more of his opinions, it could have spent a day deposing him. Neither Defendants
16 nor Dr. Shields can be faulted for Plaintiff's strategic decision not to take a
17 deposition. Though specific Spokane River exposure levels, pathways and body
18 burdens do not in any way affect Dr. Shields' opinions, Plaintiff is free to cross-
19 examine him on his knowledge thereof at trial.

20 **2. Dr. Shields' opinions regarding IARC's PCB Working Group are**
admissible and based upon proper foundation.

21 Dr. Shields offers several opinions regarding the IARC's Working Group's
22 methodology and findings. Plaintiff seeks to exclude some, but not all, of those
23 opinions. First, Plaintiff argues that testimony by Dr. Shields that the IARC did not
24 conclude PCBs were causally related to any cancers besides melanoma would

1 confuse and mislead the jury. ECF No. 388 at 6. Dr. Shields intends to opine that
2 the IARC Working Group did not report a conclusion that PCBs cause breast
3 cancer and Non-Hodgkin's Lymphoma ("NHL"). His opinion is based upon his
4 review of IARC materials, his scientific interpretation of the IARC Preamble and
5 his expertise and background in epidemiology, toxicology and clinical studies.
6 ECF No. 388-2 at 8-9, 36-38.

7 The Working Group concluded that "PCBs cause malignant melanoma." *See*
8 ECF No. 388 5. While the Working Group concluded that there were "*positive*
9 *associations*" for breast cancer and NHL, this is not a scientific conclusion of
10 *causation*. ECF No. 388-2 at 8-9, 36-38. And, according to Dr. Shields, a finding
11 by the IARC of mere positive associations "means that the consensus was that the
12 data was insufficient for classifying PCBs causally related to these cancers." *Id.* at
13 37. In short, with respect to non-melanoma cancers, IARC could not reconcile
14 inconsistent and incongruous findings of association with occupational studies in
15 which workers were exposed to levels that far exceed levels of environmental
16 exposure. *Id.* at 36-38.¹ Even Plaintiff's purported expert, Dr. David Carpenter
17 (who attended the Working Group), agrees that it did not conclude that NHL and
18 breast cancer are causally associated with PCB exposures:

19 Q. If you look on page 288, it's a carryover from 287 [of the IARC
20 Monograph] regarding strength of the association between PCBs and
human cancers. And it reads, "Increased risks for non-Hodgkin

21
22 ¹ Dr. Shields also opines that the Monograph is outdated. It did not consider over
23 seven years of literature published since the Working Group in 2013 that add to the
24 weight of the evidence that PCBs do not cause human cancers, including
melanoma, lymphoma and cancer of the breast. ECF No. 388-2 at 8.

1 lymphoma and breast cancer were also reported, both of which were
2 biologically plausible. However, the associations were not consistent
and were considered as providing limited evidence." I read that
correctly?

3 A. Correct.

4 Q. Was that, in fact, the conclusion of the IARC working group at the
conclusion of the meeting that you attended in Lyon, France?

5 A. That wording is the standard wording for IARC monographs where
6 they consider that there's strong evidence, **but not strong enough to
say that they can conclude causation.**

7 (emphasis added). *See* Declaration of Geana Van Dessel Re: Defendants'
8 Oppositions to Plaintiff's Daubert Motions, Ex. 1 (Depo. David Carpenter, Dec.
9 17, 2015, at 275:22-276:14). It is not misleading or confusing for Dr. Shields to
10 state that the Working Group did not conclude that PCBs cause cancers other than
11 melanoma. Scientifically, causation is drastically different than a mere finding of
12 an association—a concept that laypersons often misunderstand.

13 Likewise, Dr. Shields intends to testify that IARC's findings are based upon
14 the "precautionary principle." Specifically, "[a]gencies such as IARC help
15 prioritize regulatory actions. These agencies follow a precautionary principle to
16 protect public health. When these regulatory and review agencies decide that an
17 agent such as PCBs are a known human health carcinogen, it should not be inferred
18 that they will cause cancer in humans." (emphasis in the original). ECF No. 388-2
19 at 9. Plaintiff seeks to preclude this testimony, essentially on the basis that it
20 disagrees with his conclusion. This is not a basis to exclude expert testimony. *See*
21 *Humetrix, Inc., v. Gemplus S.C.A.*, 268 F.3d 910, 919 (9th Cir. 2001) ("To the
22 extent Gemplus sought to challenge the correctness of Humetrix's experts'
23 testimony, its recourse is not exclusion of the testimony, but, rather, refutation of it
24 by cross-examination and by the testimony of its own expert witnesses."). If

1 Plaintiff disagrees with Dr. Shields' conclusion that the IARC follows the
2 precautionary principal, the proper method of attacking Dr. Shields is through
3 vigorous cross-examination and presentation of contrary evidence—not a motion
4 to exclude.

5 Dr. Shields not only calls into question the methods by which IARC
6 evaluated the epidemiologic evidence, but its conclusions from that evidence. Dr.
7 Shields' opinion that the IARC Working Group's process was not transparent is
8 admissible and based on his review of the scientific literature. Dr. Shields will
9 explain that the conclusions of the Working Group are not justified when they are
10 viewed under an appropriate causal analysis, and that the Working Group lacked
11 transparency, did not adequately explain its rationale for reaching its conclusions,
12 was not qualified and included as an "invited specialist" a routinely hired gun for
13 various plaintiffs in PCB matters. *Id.* at 8-9, 36-38.

14 Plaintiff confusingly suggests that testimony regarding "lack of
15 transparency" should be excluded, because it is impermissible character evidence
16 under Rule 404(a). ECF No. 388 at 9-11. Dr. Shields is not offering evidence of a
17 "person's character" under Fed. R. Evid. 404(a). He is attacking the methodology
18 of IARC, a secretive organization, on whose findings Plaintiff and Plaintiff's
19 experts rely. This kind of challenge and criticism is well within the purview of an
20 expert witness. It is no different than one expert attacking another, following the
21 receipt of his or her expert report.

22 Next, Plaintiff suggests Dr. Shields should not be able to discuss the fact that
23 Dr. David Carpenter improperly influenced the Working Group's proceedings,
24 arguing that such testimony would lack foundation and unfairly prejudice Plaintiff.

1 ECF NO. 388 at 10-11. Dr. Shields does not intend to offer specific testimony that
2 Dr. Carpenter maliciously influenced IARC. The assistance of Dr. Carpenter, an
3 expert that routinely testifies for Plaintiff's in PCB matters, is relevant, because it,
4 along with the Working Group's inconsistent findings, improper methodology and
5 lack of transparency calls into question the accuracy, objectivity and validity of
6 any of its findings. Dr. Shields possesses an appropriate foundation to offer this
7 opinion, for which the probative value outweighs any prejudice to Plaintiff.

8 **3. Dr. Shields can testify about lung cancer and smoking, NHL and**
9 **risk assessment comparisons.**

10 Plaintiff desires to prevent Dr. Shields from testifying about certain sections
11 of his expert report, including the "Lung Cancer and Smoking Discussion" (ECF
12 No. 388-2 at 38-44), the "General Discussion of Non-Hodgkin's Lymphoma" (*Id.*
13 at 44-49) and his "opinions comparing the risk of various toxic exposures to the
14 risk presented by PCBs." (*Id.* at 33-35). According to Plaintiff, such testimony
15 should be excluded "under Rule 403 because any marginal probative value is
16 outweighed by the danger of time wasting." ECF No. 388 at 11.

17 Plaintiff concedes, however, that these topics are at least "incidental to the
18 matters at issue," and Plaintiff fails to elaborate as to why such testimony would
19 waste anyone's time. *Id.* Indeed, where Plaintiff chose not to depose Dr. Shields in
20 this matter and ask him about the subject testimony (including the reasons for its
21 inclusion in his report), it is puzzling how Plaintiff could conclude the testimony is
22 a waste of time or even speculate how long such testimony would take at trial.

23 Dr. Shields' section on smoking and lung cancer is probative and not a waste
24 of time. Dr. Shields will testify about this subject to illustrate the analysis and

1 methodology of epidemiology and causal inference, and to provide a contrast to the
2 data concerning PCBs and cancers which do not demonstrate causation. Likewise,
3 Dr. Shields' testimony on NHL is equally probative. It provides a context and
4 background regarding a specific type of cancer alleged by Plaintiff in its Complaint
5 to potentially be associated with the consumption of fish in the Spokane River. *See*,
6 *e.g.*, ECF No. 1 at ¶10 ("Human consumption of fish from affected areas of the
7 [Spokane] River may be associated with serious health risks . . . Studies have also
8 linked PCBs to increased risk for several other cancers including . . . non-
9 Hodgkin's Lymphoma."). It is hard to see how such testimony is irrelevant or a
10 waste of time when it is a subject Plaintiff decided to expressly include in its
11 Complaint and a purported basis of, among other things, its nuisance claim.

12 In the Ninth Circuit, expert testimony is relevant if it "assists the trier of fact
13 when it provides information beyond the common knowledge of the trier of
14 fact." *U.S. v. Finley*, 301 F.3d 1000, 1008 (9th Cir. 2002). To that end, courts
15 routinely admit background testimony concerning the subject of the litigation,
16 where it will assist the jury. *See e.g., U.S. v. Lewis*, 240 F.3d 866, 869-70 (10th Cir.
17 2001) (expert testimony was properly admitted to explain general requirements of
18 Oklahoma law regarding commercial area hunting licenses, where expert offered
19 no opinions as to whether that law applied to defendant); *Lewert v. Boiron, Inc.*,
20 212 F.Supp.3d 917, 933-34 (C.D. Cal. 2016) (expert testimony permissible "to
21 educate the jury on the principles of homeopathy and homeopathic dilution to
22 show why Plaintiff's evidence concerning the molecular makeup of Oscillo is not
23 dispositive of its effectiveness."); *U.S. v. Naegele*, 471 F.Supp.2d 152, 160 (D.D.C.
24 2007) (in prosecution for making material false statements in bankruptcy

1 schedules, defendant could properly call witness who was expert in bankruptcy law
2 and bankruptcy proceedings, to explain the Chapter 7 bankruptcy filing process
3 generally, as such testimony would be helpful to a jury).

4 Dr. Shields is an oncologist, hematologist, and Professor of Internal
5 Medicine and Epidemiology. He intends to testify that PCBs do not cause cancers,
6 including NHL. There can be no dispute that a background understanding of NHL
7 will assist the jury in this matter and not waste its time.

8 Finally, Plaintiff seeks to exclude “opinions comparing the risk of various
9 toxic exposures to the risk presented by PCBs. . . .” ECF No. 388 at 11 (referring
10 to and citing page 33 of Dr. Shields’ report). It is unclear what portion on page 33
11 of Dr. Shields’ expert report to which Plaintiff refers. Nonetheless, to the extent
12 Plaintiff seeks to preclude testimony comparing the risks of other types of
13 exposure to PCBs, said testimony is relevant and not a waste of time.

14 Dr. Shields does not seek to offer testimony on non-PCB risks in a vacuum.
15 The purpose of the comparison is to demonstrate the applicability of the
16 “precautionary principle” in the regulatory context. Namely, that PCB cancer risks
17 (which are the subjects of opinions by Plaintiff’s experts, including Drs. Olson and
18 DeGrandchamp), unlike for other known exposures such as smoking and pollution
19 (which are derived from and validated with actual human data), are often
20 overestimated. ECF No. 388-2 at 33-34. Thus, more than anything else, Dr.
21 Shields’ opinion is an attack on data relied upon by others, as well as those who
22 might seek to attack Dr. Shields’ thorough and systematic analysis and conclusions.
23 There is nothing wasteful about explaining this complex scientific analysis to a
24 jury so it may weigh the validity and import of certain risk and hazard assessments.

1 **III. CONCLUSION**

2 Plaintiff's motion to exclude Dr. Shields' opinions should be denied.

3 Respectfully submitted this 11th day of February 2020.

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CERTIFICATE OF SERVICE

I certify that on the 11th day of February 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF System which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

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